REMARKS

Claims 1, 2, and 8 have been amended. Claims 10-15 were canceled by way of an amendment filed December 13, 2001. New claims 16-24 are added herein by way of the present amendment. Therefore, claims 1-9 and 16-24 are currently pending.

No new matter has been added. Support for the amendments to claim 1 and claim 8 can be found in the specification at page 16, lines 13-28, for example. The amendment to claim 2 corrects an informality and is made at the request of the Examiner. Support for the amendment to claim 2 can be found in the claim itself. Support for new claims 16-24 can be found in the specification, for example, at page 4, lines 19-23; page 5, lines 8-11; page 6, lines 5-6; page 6, lines 28-30; and page 36, lines 15-17.

Reconsideration of this application and entry of the claim amendments in view of the amendments above and the discussion below is respectfully requested.

II. Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-9 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant respectfully traverses the present rejection.

Referring to claims 1-9, the Examiner concedes at page 3, lines 13-15 of the Final action mailed January 13, 2003 that the specification may provide guidelines on how to make the claimed

promoter nucleotide sequence. However, the Examiner alleges that the specification does not describe how to use the claimed promoter sequence "that is 80% identical to 18 sequential nucleotides of SEQ ID NO:3".

The present rejection is moot in view of the present amendments of claims 1 and 8. However, the Applicant puts forth the following arguments in the interest of furthering the prosecution of the application.

Pending claims 1-9 (as newly amended) recite, in part, "said [promoter] nucleotide sequence has at least 95% identity to 18 sequential nucleotides of ... SEQ ID NO 3 (pA)". The present limitation, in part, defines the metes and bounds of the claimed invention. Support for this element can be found at page 16, lines 13-28. The Applicant claims the genus of nucleotide sequences that have 95% identity to 18 sequential nucleotides of SEQ ID NO:3 which also initiate transcription of an operably linked heterologous nucleotide sequence in a plant cell.

The specification discloses how to make the claimed promoter nucleotide sequences as conceded by the Examiner. The specification discloses how to test a candidate sequence for initiation of transcription of a heterologous nucleotide sequence in a plant cell. See, for instance, the brief description of Figure 11, Figure 11 itself, and Example 10e. The present sections disclose that a promoter of the present invention linked with a uidA gene expresses GUS in plant cells and further describes using GUS enzyme activity measurements to determine if the promoter or promoter fragment initiates transcription of a heterologous gene. Referring to Figure 11, all fragments of pA (SEQ ID NO:3) that are tested show at least a 2 or 3 fold

increase in expression activity compared to the control.

One of ordinary skill in the art can use the disclosed assay to determine that a given sequence initiates transcription of a heterologous gene in a plant cell. Also in view of the disclosure, one of ordinary skill in the art can determine the percent sequence identity between a candidate sequence and 18 consecutive base pairs of SEQ ID NO:3, thereby determining whether or not the candidate sequence falls within the claimed subject matter.

Still further, the specification includes numerous working examples. For instance, promoter nucleotide sequence pB initiates transcription of an operably linked heterologous nucleic acid sequence in a plant cell (see, for example, Table 2 on page 58, line 14) and has at least 95% identity to 18 sequential nucleotides of SEQ ID NO 3 (see, for example, the C-terminal 18 sequential nucleotides of SEQ ID NO 4 (pB) which have 100% sequence identity to the C-terminal 18 sequential nucleotides of SEQ ID NO 3. Accordingly, promoter nucleotide sequence pB is a claimed promoter nucleotide sequence.

In another example, the CVP1 sequence has at least 95% identity to 18 sequential nucleotides of SEQ ID NO 3. Activity data for the CVP1 promoter operably linked with a heterologous nucleic acid sequence demonstrates that CVP1 initiates transcription in plant cells (see, e.g., page 46, lines 21-24). Accordingly, CVP1 is a claimed promoter nucleotide sequence.

In still another example, CVP2 itself (set forth in SEQ ID NO 3) has at least 95% identity to 18 sequential nucleotides of SEQ ID NO 3. Furthermore, the specification asserts and

demonstrates that CVP2 is a strong promoter in plant cells (see, e.g., page 46, line 27 through page 47, line 2). Accordingly, CVP2 is a claimed promoter nucleotide sequence.

In even further examples, 14 preferred promoter nucleotide sequences, wherein each sequence has at least 95% identity to 18 sequential nucleotides of SEQ ID NO 3 are disclosed on page 20, lines 22-26 (including promoter pB, discussed above). Activity data for each promoter nucleotide sequence driving expression of an operably linked heterologous nucleic acid sequence is disclosed, for instance, in Table 2 (page 58), Example 10, Example 11, and, as presented graphically, in Figures 9, 10, and 11.

The test for enablement is whether or not one of skill in the art would be able to make and use the claimed invention in view of the teachings of the specification and the knowledge in the art. The Applicant respectfully submits that one of ordinary skill in the present art typically has an advanced degree and years of experience in plant molecular biology. The use of promoter sequences was routine for one of ordinary skill in the art of plant molecular biology at the time the present application was filed.

In the Advisory Action mailed April 17, 2003, the Examiner asserts that "the specification only provide [*sic*] examples of promoters of 100% identity... not 80% or any percentage between 80% and 100%". See page 2 of the Advisory Action.

Thus, the Examiner admits that the specification provides examples of promoters having 100% identity "to 18 sequential nucleotides of the cassava vein mosaic virus (CsVMV) promoter

shown in SEQ ID NO 3 (pA)". However, the Examiner asserts that no examples are provided of promoters having 80% or between 80% to 100% identity. The Applicant respectfully submits that such working examples are not required for patentability. *Ex parte* Nardi and Simier, 229 USPQ 79, 80 (BOPA, 1986). The Examiner's view that a working example is required is not in keeping with the statutes or case law. Therefore, the Examiner's requirement for working examples should be withdrawn.

In view of the specification, one of ordinary skill in the art is able to make the claimed promoter nucleotide sequences (see above and, for example, page 23, lines 1-9), determine whether or not the sequence has at least 95% identity to 18 sequential nucleotide of SEQ ID NO:3, and determine whether or not the sequence initiates transcription of an operably linked heterologous sequence in a plant cell (see above and, for example, page 58, line 15). In view of the present specification and the high level of skill in art, it would have been routine work for one of skill in the art to make and use the promoter nucleotide sequence as claimed. The specification asserts and demonstrates with working examples enablement of the claimed promoter nucleotide sequence. Accordingly, the test for enablement has been met.

The Examiner has not provided any evidence to rebut the applicants' assertion of enablement, any evidence to rebut disclosures in the specification of actual promoter nucleotide sequences and their corresponding activity in plant cells, or any evidence that one of ordinary skill cannot make and use the claimed invention in view of the specification and knowledge in the art. Therefore, no *prima facie* case for lack of enablement has been made. The Applicant respectfully requests that the

present rejection be withdrawn.

III. Rejection under 35 U.S.C. §102(b)

Claims 1-9 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Calvert et al. The Applicant respectfully traverses the present rejection.

a. Claims 1-7

Referring to claims 1-7, each claim recites, in part, an isolated nucleic acid molecule. The specification discloses that an isolated nucleic acid molecule of the present invention does not contain the adjacent sequences of the CsVMV genome (see, for example, page 14, lines 27-31). The specification further discloses that a promoter nucleic acid sequence of the present invention is separated from other portions of the CsVMV genome, or is recombined with a heterologous sequence (see, for example, page 14, line 31 to page 15, line 2).

Calvert et al. does not teach an isolated nucleic acid molecule comprising a promoter nucleotide sequence as recited in the present claims and interpreted in view of the specification.

The Examiner alleges "As the sequence alignment previously provided to applicants indicates, the sequence of Calvert et al. is 98.2% overall identical to SEQ ID NO:3...". The Applicant respectfully points out that Calvert et al. did not isolate SEQ ID NO:3 from the virus genome. The sequence alignment method used by the Examiner only displays the portion of the virus genome that aligns with SEQ ID NO:3, not the entire genome of CsVMV. Calvert et al. does not teach the present alignment. The Examiner performed the sequence alignment on a date after the present application was filed. Therefore, the sequence alignment

performed by the Examiner cannot constitute prior art.

Anticipation can only be established when each and every element of the claimed invention is disclosed in a single prior art reference. Because Calvert et al., does not teach the claimed ISOLATED nucleic acid molecule, separated from the genome of CsVMV, Calvert et al. cannot be used to establish anticipation. Therefore, the applicant respectfully requests that the Examiner withdraw the present rejection of claims 1-7.

b. Claims 8-9

Referring to claims 8 and 9, each claim recites, in part, a promoter nucleotide sequence that is operatively linked to a heterologous nucleic acid sequence (see the present claims for limitations on the promoter nucleotide sequence). The specification of the present invention teaches that the heterologous nucleic acid sequence recited in claims 8 and 9 is one that originates from a foreign source (or species) or, if from the same source, is modified from its original form (see, for example, page 13, lines 20-31).

Calvert et al. does not teach the claimed promoter nucleotide sequence operably linked to a heterologous nucleotide sequence. Because Calvert et al. does not teach each and every element of the present claims, it cannot be used to establish anticipation of the claimed invention. Therefore, the applicant respectfully requests that the Examiner withdraw the present rejection of claims 8 and 9.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the amendments herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date

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